NOV - 3 2000

510(k) Summary

K002421

General Information:

This 510(k) is to provide notification of substantial equivalence for the Candela Mid IR Laser System, which is substantially equivalent to a previously marketed device intended for use in dermatology for incision, excision, ablation, and vaporization with hemostasis of soft tissue.

Submitted by:	Candela Corporation 530 Boston Post Road Wayland, MA 01778-1886
Contact Person:	Joan M. Clifford
Date prepared:	August 7, 2000
Trade Name:	Candela Mid IR Laser System
Common Name:	Dermatology Laser System
Classification:	Class II (21 CFR § 878.4810 Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology)
Predicate Device:	Laser Aesthetics CoolTouch (K962791)

Description:
The Diode laser is a Continuous Wave, diode medical laser, controlled by an embedded processor, to be used for use in dermatology incision, excision, ablation, and vaporization with hemostasis of soft tissue. The laser system operates with a Dynamic Cooling Device which provides a short burst of cryogen spray during the laser treatment. The laser output energy is delivered via an optical fiber to a handpiece which produces a circular beam with a diameter of 5 millimeters on the skin. The cryogen is delivered via a hose to a nozzle located in the handpiece. The Dynamic Cooling Device functions to cool the skin during the laser treatment minimizing thermal damage to skin during laser treatment and reducing pain associated with laser treatment.

The Candela Diode Laser system is comprised of a power supply, optical delivery system, software control system and Dynamic Cooling Device.

The Candela Mid IR Diode Laser is equipped with safety interlock systems to protect patients and operators. Users of the device make selections from a control panel to regulate operation during treatment.

The intended use of the laser system is for use in dermatology incision, excision, ablation, and vaporization with hemostasis of soft tissue.

Testing:
As a laser product, the Mid IR Diode Laser is required to conform and does conform to the Laser Performance Standard (21 CFR 1040). In addition, the device will conform to the UL 544 electrical safety standard and the Essential Requirements of the European Union Medical Device Directives.

Summary of Substantial Equivalence:
The Candela Mid IR Diode Laser has the same intended use, utilizes similar operating principles, matches key design aspects, including similar spot size, wavelength and / or the similar maximum delivered power as the predicate device. On this basis, Candela believes that its Candela Mid IR Diode Laser System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2000

Ms. Joan M. Clifford
Clinical Research Manager
Candela Corporation
530 Boston Post Road
Wayland, Massachusetts 01778

Re: K002421
Trade Name: Candela Mid IR Diode Laser System
Regulatory Class: II
Product Code: GEX
Dated: August 7, 2000
Received: August 8, 2000

Dear Ms. Clifford:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment I

510(k) Number (if known): K002421

Device Name: Candela Mid IR Diode Laser System

Indications For Use:

The Candela Mid IR Diode Laser System is indicated for the following uses:

1. For use in dermatology for incision, excision, ablation, and vaporization with hemostasis of soft tissue.

The intended use of the Candela Dynamic Cooling Device is:

1. cooling of the skin prior to laser treatment
2. reduction of pain during laser treatment

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K002421

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional format 1-2-96)